

RULEMAKING NOTICE FORM

Notice Number **2016-47**

Rule Number

**He-P 4035.13(b)(4) &
He-P 4035.73**

1. Agency Name & Address:

**NH Dept. of Health & Human Services
Division of Public Health
Radiological Health Services (RHS)
29 Hazen Drive
Concord, NH 03301**

2. RSA Authority:

RSA 125-F:5, IV & V

3. Federal Authority:

**Section 274 of the Atomic
Energy Act of 1954 as amended**

4. Type of Action:

Adoption

Amendment

Repeal

Readoption

Readoption w/amendment

X

X

5. Short Title: **Use of Byproduct Materials in the Healing Arts Quality Management Program, Written Directives and Recentness of Training**

6. (a) Summary of what the rule says and of any proposed amendments:

He-P 4035 establishes requirements and provisions for the medical production, preparation, compounding and use of byproduct material in the healing arts. He-P 4035 was readopted effective January 15, 2016. The proposal amends He-P 4035.13(b)(4) and readopts with amendment He-P 4035.73 to explicitly conform with Nuclear Regulatory Commission (NRC) regulations.

The proposed amendment to He-P 4035.13(b)(4) adds the specific requirement that an authorized user date and sign written directives. The proposed amendment to He-P 4035.73 adds to the list of sections in He-P 4035 discussing requirements for training for authorized users. He-P 4035.73 lists those sections in recentness of training where authorized users, radiation safety officers, authorized medical physicists and authorized nuclear pharmacists are required to have obtained training and experience within 7 years preceding the date of an application for licensure, or to have had on-going education and applicable experience since the training and experience was completed.

6. (b) Brief description of the groups affected:

Those affected by the proposed rules include authorized users, radiation safety officers, authorized medical physicists, authorized nuclear pharmacists.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	Federal Reg./RSA
He-P 4035.13(b) intro. & (b)(4)	10 CFR 35.40, 35.41, 35.100, 35.2040, 35.2041
He-P 4035.73	10 CFR 35.59

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Catherine Bernhard**

Title: **Rules Coordinator**

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TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:
<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **May 5, 2016**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **April 28, 2016 at 2:00 p.m.**

Place: [**DHHS Brown Bldg., Room 232, 129 Pleasant St., Concord, NH**](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **16:044**, dated **03/17/16**

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

When compared to the existing rules, the proposed rules may increase costs by an indeterminable amount to state citizens and independently owned businesses to the extent they are required to meet the revised training and experience requirements contained in the rule.

2. Cite the Federal mandate. Identify the impact of state funds:

The State of New Hampshire is an agreement state with the U.S. Nuclear Regulatory Commission (NRC), pursuant to section 274b of the Atomic Energy Act of 1954, as amended. As such, the State is required to have a program in place that is adequate and compatible with federal regulations, which these rules address. There is no impact on State funds as a result of the proposed rules.

3. Cost and benefits of the proposed rule(s):

The proposed amendment to He-P 4035.73 specifies the requirement for recentness of training for authorized users, radiation safety officers, authorized medical physicists, and authorized nuclear pharmacists engaged in the medical use of by product material in order to be consistent with NRC qualifications. There is a potential cost to those whose qualifications require additional training to meet the recent ness of experience and training requirements.

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

See response to (3) above.

C. To independently owned businesses:

See response to (3) above.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

Amend He-P 4035.13(b)(4), effective 1-15-16 (Document #11011), so that He-P 4035.13(b) intro. and (b)(4) are cited and read as follows:

PART He-P 4035 USE OF RADIONUCLIDES IN THE HEALING ARTS

He-P 4035.13 Quality Management Program and Written Directives.

(b) The quality management program shall include written policies and procedures to meet the following specific objectives:

(4) That each administration shall be in accordance with the written directive. The written directive shall be dated and signed by an authorized user. The written directive shall contain the patient or human research subject's name and the following information:

Readopt with amendment He-P 4035.73, effective 1-15-16 (Document #11011), to read as follows:

He-P 4035.73 Recentness of Training. The training and experience of an authorized user, radiation safety officer, authorized medical physicist and authorized nuclear pharmacist specified in He-P 4035.59, ~~and He-P 4035.61, He-P 4035.63-He-P 4035.71 through He-P 4035.70~~ and He-P 4035.74 shall have been obtained within the 7 years preceding the date of application, or the individual shall have had on-going education and applicable experience since the required training and experience was completed.

APPENDIX

RULE	RSA or FEDERAL REGULATION IMPLEMENTED
He-P 4035.13(b) intro. & (b)(4)	10 CFR 35.40, 35.41, 35.100, 35.2040, 35.2041
He-P 4035.73	10 CFR 35.59